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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,569	08/20/2001	Thomas Wild	9793/97	5757

757 7590 01/14/2004

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CHICAGO, IL 60611

EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/933,569

Applicant(s)

WILD ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11,12,14,15,17-19,21-23,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,12,14,15,17-19,21-23,25 and 26 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's response to the office mailed 09-17-03 is acknowledged. Currently, claims 11-12, 14-15, 17-19, 21-23, 25-26 are pending and under consideration. Claims 13 and 20 has been cancelled. Claims 11, 14, 19 and 21 has been amended.

#### ***Claim Objections***

2. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 14 is improperly dependent on a cancelled claim. Please correct.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11-12, 14-15, 17-19, 21-23, 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 11 and 19 recite "the second hapten or hapten-like molecule is identical to, or an analogue of, the first hapten or hapten-like molecule" is vague and indefinite because it is unclear as to how the 1<sup>st</sup> hapten and the 2<sup>nd</sup> hapten being identical bind at

different sites. Specifically, why is the 1<sup>st</sup> hapten able to bind the analyte specific component and not the 2<sup>nd</sup> hapten. Are the binding sites saturated, prohibiting the binding of the second hapten? Please clarify.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-12, 14-15, 17-19, 21-23, 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hevey et al (USP#4,228,237).

Hevey et al teaches methods for the detection and determination of ligands utilizing a biotin/avidin system. Claims 11-14 and 17-19 are anticipated by the reference in teaching several embodiments of an assay and methods that determine the presence and amount of a ligand. One embodiment teaches an enzyme coated avidin (assay component) bound to a biotin (1<sup>st</sup> hapten) labeled reagent that comprise of a specific binding substance (analyte specific component) for the determination of a ligand. The specific binding substance (analyte specific component) is specific for binding the ligand in the assay (see summary, lines 1-50). The ligand in this embodiment exhibits binding specificity to the specific binding substance (analyte specific component) and the exclusion of other substance in the assay (col. 4, lines 31-36). Hevey et al teaches that when the ligand is a hapten, a specific binding substance

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utilized to detect the hapten is an antibody produced when the hapten, bound to an antigenic carrier is introduced into a sample (col. 4, lines 61-65). Hevey et al teaches that during the binding steps, the reagents may be incubated individually or in particular sequence, as taught in claims 11, 17-18 (col. 2, lines 58-62). The reaction is measured by the activity of the enzyme labeled avidin (col. 3, lines 64-68 & col. 4, lines 1-5). Examples of solid carriers used in this invention range from microtiter plates to nylon beads (col. 5, lines 32-41). HRP labeled avidin is pre-reacted with biotin labeled antibody, which is added to the insoluble phase after the antigen has been incubated as taught in claim 26 (col. 9, lines 29-35). In a non-competitive binding process, the insoluble phase may be incubated with the reagents together in the presence of one another, as taught in claim 25 (col. 2, lines 58-62). With respect to hapten being identical, Hevey et al discloses that each reagent of the assay are used in excess column 10, lines 40-56 and column 13, claims 25-28). It is the Examiner's position that biotin (1<sup>st</sup> hapten) used in excess will saturate binding sites of the specific binding substance (analyte specific component) and the remaining excess biotin (2<sup>nd</sup> hapten) will bind the avidin (assay component); therefore, the teachings of identical haptens are anticipated by Hevey et al.

### ***Response to Arguments***

8. Applicant's arguments filed November 13, 2003 have been fully considered but they are not persuasive.

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Applicant argues that the reference of Hevey et al does not anticipate independent claims 11 and 19 as amended because each recites a 2<sup>nd</sup> hapten or hapten-like molecule that is identical to or an analogue of a 1<sup>st</sup> hapten or hapten-like molecule. This argument has been acknowledged but not found persuasive because the reference of Hevey et al has been reconsidered for the teachings of identical haptens and it is the Examiner's position that Hevey et al meets the claimed limitations (see explanation in 102 above).

Applicant argues that there is not motivation to combine the teaching of Hevey et al in view of Huber et al is acknowledged but is moot in view of revised 102 that include teachings of identical haptens anticipated by Hevey et al above.

Applicant argue that Hevey et al in view of Huber et al does not teach or suggest an assay component comprising a binding partner that binds both the 1<sup>st</sup> hapten and the 2<sup>nd</sup> hapten without interacting with the analyte. This argument is acknowledged but not found persuasive because Hevey et al teaches an assay component wherein avidin (assay component) binds biotin (1<sup>st</sup> hapten) which is bound to a specific binding substance (analyte specific component) which is bound to the ligand to be determined (see 102 above).

Applicant argue that the Examiner has labeled the components of the instant invention to the assay taught by Hevey et al incorrectly is acknowledged but considered moot in light of newly revised 102 above.

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**Conclusion**

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

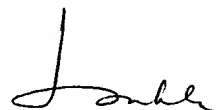
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis  
CM1, 7D16  
January 10, 2004



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